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I, Susan Mary Cowland, B.A., Dip.Trans. M.I.T.I., professional translator to Keyfax Language Services, 32 Main Street, Keyworth, Nottingham NG12 5AE, do hereby declare that I am familiar with the German and English languages, that the attached translation has been prepared by me and that it is a true translation to the best of my knowledge and ability.

S.M. Cowland



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Cover Film for Blister Packs

The invention concerns a cover film for blister packs with thermoformed or cold-
5 formed blister base parts for child-safe and senior-friendly packing of
pharmaceutical products.

To fulfil the requirements of blister packs for child safety and ease of use by the
elderly, cover films are used in the form of press-through, peel and peel-press
10 films in combination with corresponding base films and blister designs. Because
of different legislative regulations, the blister packs released in one country are
not automatically also licensed for use in another country.

In the USA, all blister packs with a new product that must be child-safe and
15 senior-friendly must be tested in a practical test. A decisive criterion here is that
the children of test age are asked to take the blister pack in their mouths and bite
on it. For this reason, in the USA laminated materials with the layer sequence
paper/PET/ aluminium/hot seal layer are used as cover films. As it is scarcely
possible now to bite through this cover film, also the product in the blister cannot
20 be removed from the packing by pressing out. The cover film is therefore
designed either as a peel or as a peel-press film, or the blister pack can be torn
open by way of opening aids from the base part. Due to the bite-proof design of
the cover film, these blister packs necessarily have cross perforations and
concealed opening aids. This leads to a substantial enlargement of the blisters in
25 comparison with a press-through packaging with a conventional press-through
film. The increase in blister dimensions of at least 3 mm in width and at least 12
mm in length leads to a lower yield by area and hence a reduction in the number
of blisters per moulding cycle in production of the blister packs.

30 In contrast to the USA, in Europe there are no uniform regulations on child-safe
and senior-friendly blister packs. The following combinations of cover films and
base parts have been tested and published in Germany:

Cover film	Base material
50 g/m ² paper / 9 µm Al film / 7 g/m ² HSL (hot seal lacquer)	PVC, ACLAR® (PCTFE)
Purelay lid (PE), 70 - 100 µm (cross perforation)	PP
23 µm PET film / peel adhesive / 20 µm Al film / 5.5 g/m ² HSL	PP, Formpack® PP (Al/PP)
40 g/m ² paper / 7 µm Al film / 3.5 g/m ² HSL	PP
Lacquer / 30 µm Al film, hard, embossed / 9 g/m ² HSL	PVC
50 g/m ² paper / 9 µm Al film / 7 g/m ² HSL	PVC
35 g/m ² paper / 9 µm Al film / 7 g/m ² HSL	PVC
Lacquer / 25 µm Al film / 9 g/m ² HSL (cross perforation)	PVC

The press-through properties are tested mechanically. Here, a semi-circular die is pressed at a defined speed onto the inside of the film which is clamped in a holder. The force necessary to press through is given in Newtons.

The following forms of cover film used in many European countries have press-through forces between 38 and 56 N (standard deviation approx. 8):

Cover film	Press through force (N)
50 g/m ² paper / 9 µm Al film / 7 g/m ² HSL	48
40 g/m ² paper / 7 µm Al film / 3.5 g/m ² HSL	41
Protective lacquer / 30 µm Al film, hard, embossed / 9 g/m ² HSL	56
35 g/m ² paper / 9 µm Al film / 7 g/m ² HSL	38
Protective lacquer / 25 µm Al film / 9 g/m ² HSL (cross perforation)	38

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In contrast to the test regulations applicable to the USA, packaging in Europe need only be tested once in the above method and is then generally licensed as child-safe for all products. As part of new draft legislation however, efforts are being made to include in European tests the bite test, compulsory in the USA, as a decisive criterion for the licensing of child-safe packing. For pharmaceutical companies, this would mean that new primary packing means must be used. This

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is associated with highly cost-intensive stability tests, the packing machines must be converted and productivity in blister production falls.

The invention is based on the object of creating a cover film which is suitable for
 5 sealing to all common base materials, which allows a child-safe and senior-friendly opening of blister packs including tropical blisters by press through, and which can be used on existing packing machines without conversion.

The object is achieved by the invention with a 5 to 30 μm thick aluminium film
 10 which on a first side

is uncoated, or

is coated with a protective lacquer with a coating weight of 0.1 to 10 g/m^2 ,
 or

is laminated with paper with a substance weight of 17 to 60 g/m^2 , or

15 is laminated with a 5 to 15 μm thick polyester film

and on the second side which is intended for sealing to a blister base part, is laminated with a non-oriented or a monoaxially or biaxially oriented plastic film on the basis of

polyvinyl chloride (PVC) with a film thickness of 10 to 40 μm , or

20 polyvinylidene chloride (PVDC) with a film thickness of 10 to 40 μm , or

polypropylene (PP) with a film thickness of 6 to 35 μm , or

polyester with a film thickness of 5 to 15 μm , or

polychlorotrifluoroethylene (PCTFE) with a film thickness of 8 to 76 μm , or

cyclo-olefin copolymers (COC) with a thickness of 10 to 40 μm .

25

The material of the plastic film which is intended for sealing to the blister base part is selected according to the material of the side of the blister base part intended for sealing. Thus, compatibility is ensured between the chemical structure of the side of the cover film according to the invention which comes into contact with the
 30 product, and the chemical structure of the side of a base film previously used and licensed which comes into contact with the product, so that the performance of new stability tests is not absolutely necessary.

The desired blister packs with the cover film according to the invention can be produced on existing machines.

- 5 The aluminium film preferably has a thickness of 7 to 30 μm .

Preferably, the protective lacquer layer on the first side of the aluminium film comprises a lacquer based on watery or organic solvents on the basis of nitrocellulose, epoxy resin, urea resin, melamine resin, polyester, polyurethane or
10 mixtures of the said lacquer raw materials, where the preferred coating weight of the protective lacquer layer is 0.5 to 5 g/m^2 .

The paper on the first side of the aluminium film can be glassine paper, glassine-substitute paper, coated or satinised paper with a preferred substance weight of
15 19 to 50 g/m^2 .

Preferably, the paper or polyester film on the first side of the aluminium film is pasted to the aluminium film with a watery, a solvent-based or a solvent-free adhesive.
20

The plastic film on the second side of the aluminium film can be pasted to the aluminium film with a watery, a solvent-based or a solvent-free adhesive or by extrusion laminating.

- 25 In a blister pack with a blister base part and a cover film according to the invention sealed to the blister base part, the blister base part comprises, at least on the side which is sealed to the cover film, a material whose chemical structure is compatible with that of the plastic film which is sealed to the blister base part. Preferably, the blister base part, at least on the side sealed to the cover film,
30 comprises the same material as the plastic film which is sealed to the blister base part.

Examples of materials used for the production of blister base parts are films of PVC, PVDC, PP, PET, PE and laminated films such as PVC/ACLAR® (PCTFE), PVC/PVDC and COC or FORMPACK® (Al-Al blister).

- 5 It should be stated here that both the cover film and the base film can be printed.

The table below gives examples of cover films according to the invention with associated press-through force. The term "outer coating" indicates the coating of the aluminium film which is directed towards the outside, and the term "inner coating" indicates that intended for sealing to the blister base part, in each case stating the substance weight for lacquer and for paper coating or the film thickness for film coating, and the type of connection between the coating and the aluminium film.

Example	Outer coating	Aluminium film	Inner coating	Press through force (N)
1	Protective lacquer 1.0 g/m ² , lacquered	20 µm, hard	PVC film, 15 µm, lacquer-laminated	44
2	Protective lacquer 1.0 g/m ² , lacquered	25 µm, soft	PVC film, 25 µm, lacquer-laminated	54
3	Paper 21 g/m ² , laminated	20 µm, hard	PVC film, 15 µm, lacquer-laminated	59
4	Protective lacquer 1.0 g/m ² , lacquered	20 µm, hard	PVC film, 25 µm, lacquer-laminated	61
5	Protective lacquer 1.0 g/m ² , lacquered	20 µm, hard	PVDC film, 25 µm, lacquer-laminated	77
6	Protective lacquer 1.0 g/m ² , lacquered	20 µm, hard	PVC film, 30 µm, lacquer-laminated	105
7	Protective lacquer 1.0 g/m ² , lacquered	20 µm, hard	PVC film, 40 µm, lacquer-laminated	48
8	Protective lacquer 1.0 g/m ² , lacquered	20 µm, hard	ACLAR® film, 15 µm, lacquer-laminated	76
9	PET film 7 µm, laminated	9 µm, soft	PET film, 7 µm, laminated	94
10	Protective lacquer 1.0 g/m ² , lacquered	20 µm, hard	Monoax. PP film, 30 µm, lacquer-laminated	89

11	Protective lacquer 1.0 g/m ² , lacquered	20 µm, hard	Monoax. PP film, 20 µm, extrusion- laminated (7 g/m ²)	90
12	Protective lacquer 1.0 g/m ² , lacquered	25 µm, hard	Monoax. PVC film, 35 µm, extrusion- laminated (7 g/m ²)	48
13	Glassine paper 35 g/m ² , laminated	9 µm, soft	PVC film, 15 µm, lacquer-laminated	20
14	Protective lacquer 1.0 g/m ² , lacquered	20 µm, hard	COC film, 20 µm, lacquer-laminated	

Claims

1. Cover film for thermoformed or cold-formed blisters for child-safe and senior-friendly packing of medicines and medicinal products, characterised by

5 a 5 to 30 μm thick aluminium film which on a first side

 - is uncoated, or
 - is coated with a protective lacquer with a coating weight of 0.1 to 10 g/m^2 , or
 - 10 is laminated with paper with a substance weight of 17 to 60 g/m^2 , or
 - is laminated with a 5 to 15 μm thick polyester film

and on the second side which is intended for sealing to a blister base part, is laminated with a non-oriented or a monoaxially or biaxially oriented plastic film on the basis of

 - 15 polyvinyl chloride (PVC) with a film thickness of 10 to 40 μm , or
 - polyvinylidene chloride (PVDC) with a film thickness of 10 to 40 μm ,

or

 - polypropylene (PP) with a film thickness of 6 to 35 μm , or
 - polyester with a film thickness of 5 to 15 μm , or
 - 20 polychlorotrifluoroethylene (PCTFE) with a film thickness of 8 to 76 μm , or
 - cyclo-olefin copolymers (COC) with a thickness of 10 to 40 μm .
2. Cover film according to claim 1, characterised in that the aluminium film is

25 in the soft or hard state or has a defined hardness.
3. Cover film according to claim 1 or 2, characterised in that the aluminium film is 7 to 30 μm thick.
- 30 4. Cover film according to any of claims 1 to 3, characterised in that the protective lacquer layer on the first side of the aluminium film comprises a lacquer based on watery or organic solvents on the basis of nitrocellulose,

epoxy resin, urea resin, melamine resin, polyester, polyurethane or mixtures of the said lacquer raw materials.

5. Cover film according to claim 4, characterised in that the coating weight of the protective lacquer layer is 0.5 to 5 g/m².
- 5 6. Cover film according to any of claims 1 to 3, characterised in that the paper on the first side of the aluminium film is glassine paper, glassine-substitute paper, coated or satinised paper.
- 10 7. Cover film according to claim 6, characterised in that the paper has a substance weight of 19 to 50 g/m².
8. Cover film according to any of claims 1 to 3, characterised in that the paper or the polyester film on the first side of the aluminium film is pasted to the aluminium film with a watery, a solvent-based or a solvent-free adhesive.
- 15 9. Cover film according to any of claims 1 to 8, characterised in that the plastic film on the second side of the aluminium film is pasted to the aluminium film with a watery, a solvent-based or a solvent-free adhesive or by extrusion laminating.
- 20 10. Blister pack with a blister base part and a cover film sealed to the blister base part, characterised in that the cover film is a 5 to 30 µm thick aluminium film which on a first side
 - 25 is uncoated, or
 - is coated with a protective lacquer with a coating weight of 0.1 to 10 g/m², or
 - is laminated with paper with a substance weight of 17 to 60 g/m², or
 - is laminated with a 5 to 15 µm thick polyester film
 and on the second side which is intended for sealing to a blister base part,
 - 30 is laminated with a non-oriented or a monoaxially or biaxially oriented plastic film on the basis of
 - polyvinyl chloride (PVC) with a film thickness of 10 to 40 µm, or

16. Blister pack according to any of claims 10 to 13, characterised in that the paper on the first side of the aluminium film is glassine paper, glassine-substitute paper, coated or satinised paper.
- 5 17. Blister pack according to claim 16, characterised in that the paper has a substance weight of 19 to 50 g/m².
- 10 18. Blister pack according to any of claims 10 to 13, characterised in that the paper or the polyester film on the first side of the aluminium film is pasted to the aluminium film with a watery, a solvent-based or a solvent-free adhesive.
- 15 19. Blister pack according to any of claims 10 to 18, characterised in that the plastic film on the second side of the aluminium film is pasted to the aluminium film with a watery, a solvent-based or a solvent-free adhesive or by extrusion laminating.